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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,913	08/06/2001	Zuomei Li	106101.145	8110

7590

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Wayne A. Keown, Ph.D.  
500 West Cummings Park, Suite 2900  
Woburn, MA 01801

EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

12

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/817,913

Applicant(s)

LI ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to an oligonucleotide that inhibits the expression of one or more specific histone deacetylase isoforms, classified in class 536, subclass 24.5.
- II. Claims 26-33, drawn to a method of inhibiting the expression of one or more histone deacetylase isoforms in a cell, classified in class 435, subclass 6.
- III. Claims 34-37 and 44-48, drawn to a method of inhibiting cell proliferation in a cell, including a cell in an animal, classified in class 514, subclass 44.
- IV. Claims 38-41, drawn to a method for identifying a histone deacetylase isoform required for cell proliferation, classified in class 435, subclass 6.
- V. Claims 42 and 43, drawn to a method for identifying a histone deacetylase isoform required for induction of cell differentiation, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide of Group I can be used in a materially different method, for example, as a probe in an in vitro detection method, which is materially different than the method of inhibiting of Group II.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide of Group I can be used in a materially different method, for example, as a probe in an in vitro detection method, which is materially different than the method of inhibiting cell proliferation in a cell or animal of Group III.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide of Group I can be used in a materially different method, for example, as a probe in an in vitro detection method, which is materially different than the method of identifying a histone deacetylase isoform of Group IV.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide of Group I can be used in a materially different method, for example, as a probe in an in vitro detection method, which is materially different than the method of identifying a histone deacetylase isoform of Group V.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group II have the effect of inhibiting the expression of a histone deacetylase, whereas the methods of Group III have the effect of inhibiting cell proliferation in a cell or animal.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group II have the effect of inhibiting the expression of a histone deacetylase, whereas the methods of Group IV have the effect of identifying a histone deacetylase isoform required for cell proliferation.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group II have the effect of inhibiting the expression of a histone deacetylase, whereas the methods of Group V have the effect of identifying a histone deacetylase isoform required for cell differentiation.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group III have the effect of inhibiting cell proliferation in a cell, including a cell in an animal, whereas the methods of Group IV have the effect of identifying a histone deacetylase isoform required for cell proliferation.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group III have the effect of inhibiting cell proliferation in a cell, including a cell in an animal, whereas the methods of Group V have the effect of identifying a histone deacetylase isoform required for induction of cell differentiation.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group IV have the effect of identifying a histone deacetylase isoform required for induction of cell differentiation, whereas the methods of Group V have the effect of a histone deacetylase isoform required for cell proliferation.

Further, for each of the Inventions I-V, a further restriction is imposed to elect one Invention wherein the Invention is restricted to a single oligonucleotide. Applicant must elect one oligonucleotide sequence for the elected method or composition of Groups I-V, selected

Art Unit: 1635

from one of the following: either an oligonucleotide complementary to a portion of either SEQ ID NO:2, 4, 6, 8, 10, 12, 14, 16 or 18 or an oligonucleotide selected from SEQ ID NO:17, 18, 20, 22, 24, 26, 28, 29, 31, 32 or 33. Each of these inventions is distinct and patentable from each other in that the oligonucleotides inhibit separate and distinct isoforms of histone deacetylase and each oligonucleotide has a separate and distinct structure (i.e. nucleotide sequence), requiring a separate and distinct search. Furthermore, a search of more than one sequences claimed for each of the Inventions I-V presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) sequence for the elected Invention. Applicant should note, this is an election of a single invention and is not a species election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each individual nucleotide sequence not required for any other claimed nucleotide sequence, which would require a separate and distinct search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
June 22, 2003

  
KAREN LACOURCIERE  
PATENT EXAMINER